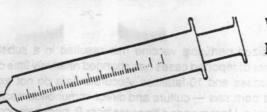
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Part I of Two Parts

# Diphtheria, Tetanus, and Pertussis: Guidelines for Vaccine Prophylaxis and Other Preventive Measures

This is a revision of the 1977 ACIP statement on diphtheria, tetanus, and pertussis. It includes a review of the epidemiology of these diseases, a description of the available immunobiologic preparations, the appropriate immunization schedules, and precautions or contraindications to vaccine use. It contains no major changes in immunization policy.

### INTRODUCTION

Simultaneous immunization against diphtheria, tetanus, and pertussis during infancy and childhood has been a routine practice in the United States since the late 1940s. It has played a major role in markedly reducing the incidence of cases and deaths from each of these diseases.

#### DIPHTHERIA

Diphtheria has declined remarkably in the United States in recent years. From 1970 through 1976, an average of 248 cases were reported annually. Since then, the average has been 56. However, diphtheria remains a serious disease. About 5%-10% of respiratory diphtheria cases are fatal, the highest case-fatality ratios being in the very young and the elderly.

At one time respiratory diphtheria was common and occurred primarily in children. Now it is rare, especially in children. This is due, in part, to an apparently reduced circulation of toxigenic strains of Corynebacterium diphtheriae and to an increased proportion of children who are adequately immunized. Most cases, both in children and adults, occur in unimmunized or inadequately immunized persons. The age distribution of recent cases and the results of serosurveys conducted in the United States suggest that many American adults are not protected.

Toxigenic and nontoxigenic strains of C. diphtheriae can cause disease. However, only strains that produce toxin result in the common complications of myocarditis and neuritis. Furthermore, toxigenic strains are more often associated with severe or fatal illness in noncutaneous (respiratory or other mucosal surface) infections, and a higher proportion of them are recovered from respiratory than from cutaneous infections. C. diphtheriae can contaminate the skin of certain individuals, usually at the site of a wound. Although a sharply demarcated lesion with a pseudomembraneous base often results, the appearance may not be distinctive and the infection can be confirmed only by culture. Usually other bacterial species can also be isolated. Cutaneous diphtheria most commonly affects certain groups of American Indians and indigent adults.

## **TETANUS**

The incidence of tetanus has decreased dramatically with routine use of tetanus toxoid. Nonetheless, the number of reported cases has remained relatively constant in the last decade (approximately 100 cases annually). In 1980, 95 tetanus cases were reported from 33 states. In recent years, approximately two-thirds of patients have been ≥ 50 years old. The disease has occurred almost exclusively in persons who are unimmunized or inadequately immunized or whose immunization history is unknown.

In 10%-20% of recent tetanus cases, no wound could be implicated. In 5%-10%, only minor acute wounds or chronic skin lesions, such as decubitus ulcers, were reported.

Neonatal tetanus occurs in infants born under conditions where infection is likely to mothers who are not adequately immunized. Immune pregnant women confer protection to their infants through transplacental maternal antibody.

Spores of Clostridium tetani are ubiquitous, and there is essentially no natural immunity to tetanus toxin. Thus, universal, primary immunization with subsequent maintenance of adequate antitoxin levels by means of appropriately timed boosters is necessary to protect all age groups. Tetanus toxoid is highly effective and generally induces protective levels of serum antitoxin which persist for at least 10 years after full immunization.

#### **PERTUSSIS**

General use of standardized pertussis vaccine has resulted in a substantial reduction in cases and deaths from pertussis. However, the number of reported cases has changed relatively little during the last 10 years, when there has been an annual average of 2,300 cases and 10 fatalities. Accurate data do not exist since many cases go unrecognized and diagnostic tests for *Bordetella pertussis* — culture and direct-immunofluorescence assay — may be unavailable, difficult to perform, or incorrectly interpreted. Most reported illnesses from *B. pertussis* occur in infants and young children; two-thirds of reported deaths occur in children less than 1 year old. In older children and adults, who may serve as reservoirs of infection, the disease may result in nonspecific symptoms of bronchitis or a severe upper respiratory tract infection; pertussis may not be diagnosed because classic signs, especially the inspiratory whoop, are often absent.

Pertussis is highly communicable (attack rates of over 90% have been reported for unimmunized household contacts). It frequently is associated with complications, severe sequelae, and a high case-fatality ratio in infants. Vaccination early in life is essential.

Because the incidence and severity of pertussis decrease with age and because the vaccine may cause side effects and adverse reactions, routine pertussis immunization is neither needed nor recommended for persons 7 years old or older, except under unusual circumstances (see "VACCINE USAGE").

## PREPARATIONS USED FOR IMMUNIZATION

Diphtheria and tetanus toxoids are prepared by formaldehyde treatment of the respective toxins and standardized for potency according to the regulations of the Food and Drug Administration. The Lf content (quantity of toxoid as assessed by flocculation) varies among the different products but does not necessarily reflect potency. The concentration of diphtheria toxoid in preparations intended for use in adults is lower than that of the pediatric formulation; this is to facilitate lower dosage because adverse reactions are thought to be related to both dose and age.

Tetanus toxoid is available in fluid and aluminum salt adsorbed forms. Although the rate of seroconversion is essentially equivalent with either form, adsorbed toxoids induce more persistent antitoxin titers and are therefore strongly recommended for both primary and booster injections.

Pertussis vaccine is a suspension of inactivated *B. pertussis* bacteria. Potency is assayed by comparison with the U.S. Standard Pertussis Vaccine in mouse protection tests. Each dose of vaccine contains an estimated 4 protective units.

The 2 toxoids and the pertussis vaccine are currently available in the United States singly and in various combinations:

- Diphtheria and Tetanus Toxoids and Pertussis Vaccine Adsorbed (DTP) and Diphtheria and Tetanus Toxoids
   Adsorbed (For Pediatric Use) (DT) are combinations recommended for use in infants and children less than 7 years
   old.
- 2. Tetanus and Diphtheria Toxoids Adsorbed (For Adult Use) (Td) is a combined preparation recommended for use in persons 7 years old and older. This product contains a limited amount of diphtheria antigen (not more than 2 Lf/dose).
- 3. Single antigen products, such as Pertussis Vaccine Adsorbed (P), Tetanus Toxoid and Tetanus Toxoid Adsorbed (T), and Diphtheria Toxoid Adsorbed (D), are available for situations when combined antigens should not be used.

## **VACCINE USAGE**

(See also ACIP. General recommendations on immunization. MMWR 1980;29:76,81-3.)

## **Dosage and Administration**

These products should be injected according to the recommendations in the manufacturers' package inserts. Adsorbed preparations should be administered intramuscularly. Jet injection may be associated with more frequent local reactions.

### **Primary Immunization**

Children 6 weeks through 6 years old (up to the seventh birthday) (Table 1): One dose of DTP should be given intramuscularly on 4 occasions, the first 3 doses at 4- to 8-week intervals, beginning when the infant is approximately 6 weeks-2 months of age. The fourth (reinforcing) dose is given approximately 1 year after the third to maintain adequate antibody levels for the ensuing preschool years. This dose is an integral part of the primary immunizing course. If a contraindication to pertussis vaccination exists, DT should be substituted for DTP (see "PRECAUTIONS AND CONTRAINDICATIONS").

Children 7 years old and older and adults (Table 2): A series of 3 doses of Td should be given intramuscularly; the second dose should be given 4-8 weeks after the first, and the third dose, 6 months to 1 year after the second. Td is the agent of choice for immunization of all patients 7 years old and older because side effects from higher doses of diphtheria toxoid are more common in older children and adults, and because pertussis in these age groups is infrequent and less severe than in infants and young children.

Interruption of primary immunization schedule: Interrupting the recommended schedule or delaying subsequent doses does not reduce the ultimate immunity. There is no need to restart a series regardless of the time elapsed between doses.

TABLE 1. Routine diphtheria, tetanus, and pertussis immunization schedule summary for children less than 7 years old, 1981\*

Dose	Age/interval	Product
Primary 1 Primary 2† Primary 3† Primary 4†	6 weeks old or older 4-8 weeks after first dose 4-8 weeks after second dose approximately 1 year after third dose	DTP‡ DTP DTP
Booster	4-6 years old, prior to entering kindergarten or elementary school (not necessary if fourth primary immunizing dose administered after fourth birthday)	DTP
Additional Boosters	every 10 years after last dose	Td

<sup>\*</sup>Important details are in the text.

†Prolonging the interval does not require restarting series.

**‡DT**, if pertussis vaccine is contraindicated.

TABLE 2. Routine diphtheria and tetanus immunization schedule summary for persons 7 years old and older, 1981\*

Dose	Age/interval		Product
Primary 1	first visit	13	UCOSIS - bTcc.AAR.
Primary 2†	4-8 weeks after first dose		Td TX
Primary 3†	6 months-1 year after second dose		Td
Boosters	every 10 years after last dose	2851	Td Agent

<sup>\*</sup>Important details are in the text.

Interruption of primary immunization schedule: Interrupting the recommended schedule or delaying subsequent doses does not reduce the ultimate immunity. There is no need to restart a series regardless of the time elapsed between doses.

#### **Booster Immunization**

Children 4 through 6 years (up to the seventh birthday): Those who received all 4 primary immunizing doses before their fourth birthday should receive a single dose of DTP just before entering kindergarten or elementary school. This booster dose is not necessary if the fourth dose in the primary series was given after the fourth birthday.

Persons 7 years old and older: Tetanus toxoid should be given with diphtheria toxoid as Td every 10 years. If a dose is given sooner as part of wound management, the next booster is not needed for 10 years thereafter (see "TETANUS PROPHYLAXIS IN WOUND MANAGEMENT"). More frequent boosters are not indicated and have been reported to result in an increased incidence and severity of adverse reactions.

## **Special Considerations**

Persons recovering from tetanus or diphtheria: Tetanus or diphtheria infection often does not confer immunity; therefore active immunization should be initiated or completed during convalescence.

Children recovering from pertussis: Children who have recovered from bacteriologically confirmed pertussis need not receive more pertussis vaccine. However, without reliable laboratory confirmation, DTP immunization should be completed because presumptive pertussis may have been caused by agents like other Bordetella species or some viruses.

Neonatal tetanus prevention: An unimmunized pregnant woman whose delivery may occur under circumstances and in surroundings where the infant could become infected should be immunized against tetanus with Td. The risk of neonatal tetanus is minimal if a previously unimmunized mother has received at least 2 properly spaced doses of toxoid before delivery. Inadequately immunized pregnant women or those immunized more than 10 years previously should have a booster dose.

Pertussis immunization for persons 7 years old and older: Routine immunization against pertussis is not recommended for those 7 years old and older. In exceptional cases, such as persons with chronic pulmonary disease exposed to children with pertussis, or health-care personnel exposed during nosocomial or community outbreaks, a booster dose of adsorbed pertussis vaccine may be useful. A dose of 0.20-0.25 ml is most often used for adults. There is insufficient evidence to warrant routine pertussis vaccination of all hospital personnel.

### **FOOTNOTES**

<sup>†</sup>Projonging the interval does not require restarting series.

<sup>1</sup> Immunization Practices Advisory Committee. Diphthena and tetanus toxoids and pertussis vaccine, MMWR 1977.26.401-2, 407

<sup>2</sup> Distributed by the Michigan State Department of Public Health within that state; available for use outside Michigan under special circumstances, by consultation

	STATE					REGIONS				
DISEASE	THIS	LAST MONTH	TOTAL TO DATE 1981 1980		MEAN 5 YEAR TO DATE	THIS MONTH				1
Service Control	MONTH					N.W.	N.	s.w.	C.	E.
CHICKENPOX	50	43	1723	483	890.4	11	5	5	3	26
MEASLES	9		18	339	1416.4	-	-	9	-	-
MUMPS	7	2	134	87	148.8	1	-	-	-	6
PERTUSSIS	1	1	10	10	16.2	-	1	-	-	-
RUBELLA	3	N SHANK ISH	9	42	270.0	2	-	-	7	-
MENINGITIS - ASEPTIC	18	16	274	188	180.4	7	2	5	0	4
BACTERIAL	28	15	224	189	142.2	4	9	8	2	4
ENCEPHÁLITIS - INFECTIOUS	3	1	40	35	29.0	_	-	1	-	2
POST-INFECTIOUS	2	-	6	7	8.6	1	4	mu-gn	-	
HEPATITIS A (INFECTIOUS)	6	15	200	310	306.8	7	2	7	2	
B (SERUM)	43	42	537	520	362.2	5	14	7	10	
SALMONELLOSIS	96	76	1572	1303	962.4	10	9	16	32	29
SHIGELLOSIS	34	39	1211	198	163.8	3	3	4	24	-
TUBERCULOSIS - PULMONARY	61	48	553	545	-	-	-	nis Tori	-	-
EXTRA-PULMONARY	14	12	115	107	81 -	-	- 5	na tar	-	
SYPHILIS (PRIMARY & SECONDARY)	37	60	733	591	561.6	4	6	3	6	18
GONORRHEA	1792	1653	20,762		24,418.0	-	-	10/2006	-	-
ROCKY MOUNTAIN SPOTTED FEVER		1	104	96	110.2	W 1/2 9	1200	mr 2 min	-	
RABIES IN ANIMALS	24	27	166	35	26.0	10	10	4	-	
MENINGOCOCCAL INFECTIONS	7	9	103	67	62.0	2	-	2	2	1
INFLUENZA	22	43	5001	1191	4846.2	1	-	21	-	1
MALARIA	_	4	33	65	30.0	-	-	:00:200	-	
OTHER: Hepatitis Unspec.	9	11	177	169	181.4	-	1	1	3	4
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COUNTIES REPORTING ANIMAL RABIES: Fauquier-8 rac.; Loudoun-9 rac., 1-skunk; Scott-4 skunk; Clarke-1 skunk; Rockinghamsses-1 rac. Occupational pneumoconiosis-5; Occupational dermatoses-2;

Occupational hearing loss-5; Asbestosis-7; Byssinosis-1

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